

**National Institute for Health and Care Excellence**  
**IP1862 Ab interno canaloplasty for open-angle glaucoma**

**IPAC date: 11<sup>th</sup> August 2022**

<b>Com . no.</b>	<b>Consultee name and organisation</b>	<b>Sec. no.</b>	<b>Comments</b>	<b>Response</b>
				Please respond to all comments
1	Consultee 1 Royal College of Ophthalmologists	Lay description	The "tiny tube" can be a commercially available device but non-expensive alternatives may used, e. g., a suture.	Thank you for your comment. The lay description is not typically changed after consultation.
2	Consultee 1 Royal College of Ophthalmologists	1.6	Further research should perhaps report comparative effectiveness and cost-effectiveness with other glaucoma procedures	Thank you for your comment. Cost- and comparative-effectiveness are not part of the remit of the IP programme.
3	Consultee 1 Royal College of Ophthalmologists	2.3	Treatment usually involves laser trabeculoplasty and eye drops... .	Thank you for your comment. Both laser trabeculoplasty and eye drops are included in the current treatments section.
4	Consultee 1 Royal College of Ophthalmologists	2.4	It is typically done under local anaesthetic.	Thank you for your comment. Section 2.4 of the guidance was amended to: 'It is usually done under local anaesthesia, but general anaesthesia can be used.'
5	Consultee 1 Royal College of Ophthalmologists	3.1	You may wish to add that current evidence is very limited due to the nature of studies, i.e., high risk of bias, no RCTs	Thank you for your comment. The committee considered this comment but decided not to change the guidance.
6	Consultee 1	3.2	These are core outcomes for glaucoma trials that have been identified by clinicians and also by patients.	Thank you for your comment.

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	Royal College of Ophthalmologists		You may wish to see:  Ismail R, et al. Consensus on Outcome Measures for Glaucoma Effectiveness Trials: Results From a Delphi and Nominal Group Technique Approaches. J Glaucoma. 2016 Jun;25(6):539-46.	Please respond to all comments  Consultee agrees with the key efficacy outcomes. Consultee cites the following publication:  <ul style="list-style-type: none"> <li>Ismail R, et al. Consensus on Outcome Measures for Glaucoma Effectiveness Trials: Results From a Delphi and Nominal Group Technique Approaches. J Glaucoma. 2016 Jun;25(6):539-46.</li> </ul> This is a Delphi study that aimed to identify key glaucoma outcomes and not directly relevant to the IP being considered.
7	Consultee 1 Royal College of Ophthalmologists	3.3	Further surgery to control IOP (for glaucoma control) should not be considered a safety event... just lack of efficacy. However further surgery to manage a complication should be a safety event.	Thank you for your comment.  Section 3.2 of the guidance was amended to: 'need for further IOP-controlling surgery'  Section 3.3 of the guidance was amended to: 'need for further surgery for complications'
8	Consultee 1 Royal College of Ophthalmologists	Overview – General	The available data on this procedure is all observational without control group or randomisation. There are no RCTs and as such the expense and risk of surgery are hard to justify outside of a randomised controlled trial	Thank you for your comment.  The committee considered this comment but decided not to change the guidance.
9	Consultee 1 Royal College of Ophthalmologists	Overview – Safety summary	Failure to achieve the surgical goal (IOP reduction) requiring further surgery may not be considered a safety issue	Thank you for your comment.  The overview was updated so that the need for further surgery section was included in the efficacy summary.
10	Consultee 1 Royal College of Ophthalmologists	Overview – Safety summary	This is very high compared to alternative procedures and raises significant safety concerns.	Thank you for your comment.  The committee considered this comment but decided not to change the guidance.

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			[This comment was in reference to the following text: 'The before-and-after study of 71 eyes reported 12 cases of IOP spikes over 30 mmHg (Gillman, 2021).']	Please respond to all comments
11	Consultee 1 Royal College of Ophthalmologists	Overview – anecdotal and theoretical adverse events	I concur with this list and remain concerned about the procure being done outside of an RCT	Thank you for your comment. The committee considered this comment but decided not to change the guidance.
12	Consultee 1 Royal College of Ophthalmologists	Overview – General	have you assessed the (very extensive) financial conflicts of interests of the authors of these studies?	Thank you for your comment. Relevant conflicts of interest are extracted in the individual study summaries in the overview. The committee considered this comment but decided not to change the guidance.
13	Consultee 1 Royal College of Ophthalmologists	Overview – summary of key evidence	These studies have very high risk of bias. I would suggest that there is a more explicit statement regarding the poor quality of current evidence.	Thank you for your comment. The committee considered this comment but decided not to change the guidance.
14	Consultee 1 Royal College of Ophthalmologists	Overview – Validity and generalisability	HUGE risk of bias, poor quality studies - cannot possibly justify this being done by rank and file surgeons at considerably greater cost to limited budgets than the proven alternatives.	Thank you for your comment. Please note that cost-effectiveness is not part of the remit of the IP programme. The committee considered this comment but decided not to change the guidance.
15	Consultee 2 Sight Sciences Inc. Company	General	There are 4 key points that we feel need highlighting to NICE regarding this draft guidance: 1. The intension to give a recommendation of 'special arrangements' for ab interno canaloplasty is inconsistent with IPG591 (ab externo canaloplasty). The evidence for ab externo canaloplasty is similar to	Thank you for your comments. 1. Consultee disagrees with the main recommendation and argues that there is similar evidence for ab interno canaloplasty and for ab externo canaloplasty, and that the

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			<p>that for ab interno. Many surgeons regard the ab interno approach as less time consuming, needing less staff in theatre and associated with a lower risk of complications. Yet the proposed recommendations will give a more favourable assessment of the ab externo approach compared to ab interno. This inconsistency may be interpreted by NHS stakeholders as ab externo canaloplasty being safer and more effective than ab interno canaloplasty. The clinical evidence does not support this position. We would propose that a recommendation of 'standard arrangements' is given to ab interno canaloplasty.</p> <p>2. At a time when the NHS is struggling with capacity in glaucoma clinics, NICE intend to reduce the assessment level of canaloplasty from 'standard arrangements' to 'special arrangements'. This may prevent patients and surgeons from having access to a minimally invasive surgical solutions that can alleviate capacity issues rather than add to them. This may lead to an increase in capacity issues which in turn may result in increased visual impairment/blindness due to glaucoma.</p> <p>3. It must be considered that a high percentage of ab interno canaloplasty in the UK is carried out in conjunction with a trabeculotomy procedure as the two procedures complement each other from an IOP lowering and a medication reduction perspective. All ab interno canaloplasty procedures include at least a minimal trabeculotomy/goniotomy in order to access Schlemm's canal. Performing these procedures together has obvious cost savings and patient benefits.</p>	<p>Please respond to all comments</p> <p>current recommendations will push more surgeons towards the ab externo technique.</p> <p>2. Consultee discusses the impact of the draft recommendations on NHS capacity issues. Please note that this guidance for ab interno canaloplasty does not change the recommendations for ab externo canaloplasty for primary open-angle glaucoma (IPG591; standard arrangements).</p> <p>3. Consultee highlights the possible combined use of ab interno canaloplasty and trabeculotomy. There were several studies identified in the literature that used both techniques. Given that this guidance only considers ab interno canaloplasty, only those studies that used canaloplasty alone were included in the key evidence of the overview. Studies that used the combined technique were included in the appendix.</p> <p>4. One of the studies included in the key evidence reported a device malfunction as an adverse event. As the IP programme produces guidance on procedures rather than individual devices, this adverse event was included in the overview. However, the overview was updated to reflect that this device is a precursor of the device currently available.</p> <p>The committee considered this comment but decided not to change the guidance.</p>

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			<p>When combined with cataract surgery, the benefits are extended further. Ab externo canaloplasty would not be used in conjunction with cataract surgery yet NICE's proposed recommendation may limit access of this combined surgery for patients compared to current treatment pathways.</p> <p>4. The VISCO360 device (a predicate device to OMNI Surgical System) has not been available to surgeons for over 3 years yet NICE have referenced a section on 'device malfunction' (Pg 7 &amp; 18 of the Overview document ). We feel this is irrelevant to the production of a current IPG document.</p>	
16	Consultee 2 Sight Sciences Inc. Company	3.2	<p>Canaloplasty (with trabeculotomy), has been shown to reduce diurnal IOP fluctuation significantly in a PROSPECTIVE clinical trial including 129 patients in the analysis set. This has been published in a peer reviewed journal (Pyfer M et al. 2021.) Suppression of Diurnal (9AM–4PM) IOP Fluctuations with Minimally Invasive Glaucoma Surgery: An Analysis of Data from the Prospective, Multicenter, Single-Arm GEMINI Study. Clinical Ophthalmology 15:3931-3938. If visual field preservation is a key efficacy outcome for NICE, this paper should be considered.</p>	<p>Thank you for your comment.</p> <p>The consultee lists the following publication:</p> <ul style="list-style-type: none"> <li>Pyfer MF, Gallardo M, Campbell A, et al. (2021) Suppression of diurnal (9am-4pm) IOP fluctuations with minimally invasive glaucoma surgery: An analysis of data from the prospective, multicenter, single-arm GEMINI study. Clinical Ophthalmology 15:3931-8</li> </ul> <p>This study was included in the appendix as it involved the combined use of canaloplasty and trabeculotomy.</p>
17	Consultee 2 Sight Sciences Inc. Company	2.4	(Pg3): replace 'simultaneously' with 'sequentially'	<p>Thank you for your comment.</p> <p>Section 2.4 of the guidance was amended to: 'Some devices allow canaloplasty to be done sequentially with trabeculotomy as part of a single operation'</p>

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18	Consultee 2 Sight Sciences Inc. Company	Overview – key evidence	Tracer study (2020) - It should be understood that the IOP spikes were all transient and resolved: "Transient IOP spikes were observed in 7% of eyes for Group 1" Gillman Study (2021) - It should be understood that the majority of these were "early" IOP spikes (i.e. within the first month) which most studies do not report as adverse events as they are a common phenomenon of anterior segment surgery, often a consequence of residual OVD, or a steroid response to the standard post-op use of topical steroids. "Most frequently recorded AEs following ABIC were early post-operative IOP spikes (22.2%) and uncontrolled IOP requiring filtering surgery (13.0%).	Thank you for your comment.  Consultee provides further information about the IOP spikes reported in 2 studies. This information was added to the overview.  The committee considered this comment but decided not to change the guidance.
19	Consultee 2 Sight Sciences Inc. Company	Overview – Safety summary	The VISCO360 device is no longer marketed and has not been for >3 years. The VISCO360 device was a forerunner of the current OMNI device which has undergone modification and enhancement compared to its predecessor. Therefore, this text seems irrelevant to a current IPG.	Thank you for your comment.  One of the studies included in the key evidence reported a device malfunction as an adverse event. As the IP programme produces guidance on procedures rather than individual devices, this adverse event was included in the overview and considered by the committee. However, the overview was updated to reflect that this device is a precursor of the device currently available.
20	Consultee 2 Sight Sciences Inc. Company	Overview – Key evidence	There seems only to be commentary sections on the Gallardo study (2021) and not for the other 5 studies? Therefore we have grouped comments for ALL studies into the 'Analysis' section for the Gallardo study.	Thank you for your comment.  This was an error in the uploading of the consultation documents. All parts of the overview were available for commentary, but only Gallardo (2021) had a separate subheading on the website.

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21	Consultee 2 Sight Sciences Inc. Company	Overview – Key evidence	<p>Tracer study analysis (Pg13) : There was no adjustment for multiple comparisons - however in the case of IOP effectiveness, the p value at 12 months was &lt;.0001 so any adjustment for multiple comparisons would not have changed the conclusion of statistical significance.</p> <p>Key Findings - IPO reduction (Pg14) : The increase in IOP between 6 months and 12 months was not quite statistically significant (p=0.058)... and would have been even less close to significance had alpha been adjusted for multiple comparisons.</p> <p>Hughes study analysis (Pg16) - There was no adjustment for multiple comparisons... however, with p values of .0005 the differences would have remained statistically significant even with a multiplicity adjustment.</p> <p>Study 4 Ondrejka (2019) Pg 18: Device deficiency Visco360 – why is this relevant to the IPG overview document? The IPG process is on the procedure not the device – Visco360 has not been available to surgeons for over 3 years – how is this relevant?</p> <p>Study 5 Toneatto (2022) Pg19 – Analysis - There was no adjustment for multiple comparisons... The p values are sufficiently low to remove any doubt that significance would not have been achieved even with multiplicity adjustment.</p>	<p>Please respond to all comments</p> <p>Thank you for your comments.</p> <p>Consultee adds some further information on the statistical analysis of the key evidence studies. The multiple comparisons problem is often seen in observational research. The IP team highlight to the committee those studies in which multiplicity adjustments were made so that they can make their own assessments of statistical validity.</p> <p>The consultee is correct that for the analyses in several studies, multiplicity adjustment would likely not have changed the findings that were statistically significant. However, for analyses close to the significance level, multiplicity adjustment may have led to statistically non-significant findings, for example:</p> <ul style="list-style-type: none"> <li>Tracer (2020): In people with baseline IOP of &lt;18 mmHg (n=69 eyes at baseline; number at follow up not reported), there was a statistically significant decrease in the mean glaucoma medicine use per person from 1.1 (SD 0.9) at baseline to 0.6 (SD 0.6) at 12 months follow up (p&lt;0.05).</li> </ul> <p>The consultee also notes the device malfunction as per comment 19.</p> <p>The validity and generalisability section of the overview was amended to:</p> <p>‘However, the p-values obtained in most analyses were small enough to not be affected by adjustment for multiple comparisons.’</p>

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22	Consultee 2 Sight Sciences Inc. Company	Overview – Validity and generalisability	<p>We are not sure if the inclusion of SOAG is being viewed as a weakness/confounder - but we would argue it increases the generalizability of the results to a broader patient population.</p> <p>Selection bias is possible in retrospective studies however the Methods in these references describe just the opposite:</p> <p>Gillmann 2021: "In this retrospective study, the medical records of all patients who underwent ABiC between September 2015 and December 2019 were analysed."</p> <p>Toneatto 2022: "All adult patients (&gt;18 years old) with mild to moderate (Glaucoma Staging System 2 Stages 1 to 3) [10] OAG who had undergone ab-interno SC viscodilation were enrolled retrospectively."</p> <p>Tracer 2020: "Retrospective study of all OAG patients treated with 360-degree ab-interno viscodilation with cataract surgery by a single surgeon (NR) having 12 months of follow-up."</p> <p>Hughes 2020: "This study is a retrospective review of patient data from consecutive patients with open-angle glaucoma treated following normal clinical standard of care."</p> <p>Ondrejka 2019: "Retrospective analysis of 106 eyes from 71 consecutive patients."</p> <p>Gallardo 2021: "This retrospective, comparative, and consecutive case series..."</p> <p>Adjustment for multiple comparisons such as a Bonferroni correction generally result in splitting the "alpha" such that the threshold for statistical significance is reduced to mitigate the risk of a type 1 error (rejecting the null hypothesis when it is actually</p>	<p>The committee considered this comment but decided not to change the guidance.</p> <p>Thank you for your comments.</p> <p>The consultee highlights the inclusion of patients with different types of glaucoma, the methods used to reduce selection bias in the key evidence studies, the use of adjustment for multiple comparisons (as per comment 21), and comments on the strength of observation data over RCTs.</p> <p>The committee considered this comment but decided not to change the guidance.</p>



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			<p>true, i.e. accepting the alternative hypothesis which is usually that there IS a significant difference). The correction is dividing alpha, the original "p value" typically .05, by the number of tests. This means that if there were 10 comparisons, statistical significance would be declared for <math>p &lt; .005</math>. So - the p values in the cited references are well below this margin which means whether or not a Bonferroni correction was employed is moot.</p> <p>Gillmann 2021: All reported p values <math>&lt; .001</math>  Toneatto 2021: All reported p values <math>&lt; .001</math>  Tracer 2020: p-value for 12 month IOP reduction in high preop IOP cohort <math>&lt; .0001</math>  Hughes 2020: The mean baseline IOP reduced significantly (<math>p &lt; 0.0005</math>) at 12 months and (<math>p &lt; 0.0005</math>) at 18 months.  Ondrejka 2019: This paper DID adjust for multiple comparisons - "A paired t-test along with post hoc Tukey adjustment to account for multiplicity was done to compare IOP and the number of IOP-lowering medications with baseline."  Gallardo 2021: "A repeated-measures ANOVA test was used to compare mean IOP and number of medications between groups over time followed by a post hoc Tukey's test for multiple comparisons across the visits." AND the reported p values were <math>&lt; .001</math>.</p> <p>While RCTs are the best method to understand the treatment effect in a well-defined (usually narrowly defined) population, Retrospective data that originated in actual clinical practice (and not in a clinical trial) offers the strength of assessing performance of a device in actual use by clinicians in their day-to-day treatment of patients.</p>	

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			The populations studied were mild to moderate defined under universally accepted criteria (e.g. Hodapp-Parrish), and the surgical technique is established by the manufacturers and surgeons receive training from the manufacturer on usage irrespective of nation.	Please respond to all comments
23	Consultee 2 Sight Sciences Inc. Company	Overview – Issues for consideration by IPAC	NCT04769453: We note that the Sponsor of this study (Nova Eye) changed the status of it on CT.gov to "Recruitment Suspended" on November 16, 2021	Thank you for your comment.  As of November 2022, this trial remains suspended. However, private communication with the sponsor suggests that this trial will resume with recruitment relocated to Europe.
24	Consultee 2 Sight Sciences Inc. Company	General	We also feel that the link to the peer-reviewed study below will be informative to IPAC as it includes a video highlighting the differences between the ab externo and ab interno approaches to canaloplasty for OAG:  <a href="https://www.dovepress.com/canaloplasty-in-the-treatment-of-primary-open-angle-glaucoma-patient-s-peer-reviewed-fulltext-article-OPHT">https://www.dovepress.com/canaloplasty-in-the-treatment-of-primary-open-angle-glaucoma-patient-s-peer-reviewed-fulltext-article-OPHT</a>	Thank you for your comment.  IPAC was made aware of the video.
25	Consultee 2 Sight Sciences Inc. Company	General	We have also composed a report (attached) in response to the draft guidance using a sub-analysis of a comprehensive systematic literature review that was not available to us at the time of NICE requesting our initial evidence submission back in January. We would be grateful if this report can also be considered by IPAC. The report was too large to include in the on-line comment submission, hence me sending it separately.  <b>Executive summary</b> (extracted from report):  Canaloplasty is an effective procedure for lowering intraocular pressure (IOP) in open-angle glaucoma (OAG) and may be performed using either an ab	Thank you for your comment.  Consultee provides a report summarising data on ab interno canaloplasty and argues for standard arrangements. The executive summary of the report has been extracted and the report was included in the committee papers.  The report lists the following clinical publications, reasons for inclusion in or exclusion from the key evidence of the overview are presented: <ul style="list-style-type: none"> <li>Gallardo MJ, Sarkisian SR, Jr., Vold SD, et al. (2021) Canaloplasty and Trabeculotomy Combined with Phacoemulsification in Open-</li> </ul>

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			<p>externo (enter the eye via a conjunctival incision) or an ab interno (enter the eye via a corneal incision) approach. While both the ab interno and ab externo approaches provide similar effectiveness, the potential operative and postoperative complications are different and favour ab interno procedures, due to the need for manipulation of the conjunctiva with the ab externo approach. Conjunctival tissue that has been surgically manipulated will leave the region sutured and potentially scarred. If a subsequent intervention is performed which requires the formation of a conjunctival bleb in this sutured or scarred tissue region (e.g., a filtration surgery or insertion of long-tube devices or subconjunctival micro/minimally invasive glaucoma surgery [MIGS]), the success of this intervention can be compromised.</p> <p>By entering the eye via the cornea, ab interno canaloplasty (ABiC) does not cause conjunctival scarring. Furthermore, the incision for the ABiC is the same as the incision for cataract surgery (phacoemulsification) allowing it to be performed at the same time. This further reduces the number of surgical interventions and their associated risks, tissue manipulation or need for sutures, which is a benefit in OAG patients with cataract.</p> <p>The safety issues associated with the ab externo approach are well documented. According to the NICE IPG 591 on ab externo canaloplasty in OAG (13 September 2017), the following safety issues have been identified: IOP rises of more than 30 mmHg, hyphaema, hypotony, central retinal artery occlusion, ocular decompression retinopathy, choroidal effusion or</p>	<p>Angle Glaucoma: Interim Results from the GEMINI Study. Clinical ophthalmology (Auckland, NZ) 15:481-9.</p> <ul style="list-style-type: none"> <li>○ Included in the appendix of the original overview. Combined use of canaloplasty and trabeculotomy.</li> </ul> <ul style="list-style-type: none"> <li>● Gallardo MJ, Pyfer MF, Vold SD et al. (2022) Canaloplasty and Trabeculotomy Combined with Phacoemulsification for Glaucoma: 12-Month Results of the GEMINI Study. Clinical ophthalmology (Auckland, NZ) 16:1225-34. <ul style="list-style-type: none"> <li>○ Identified in the post-consultation literature search. Was included in the appendix of the updated overview. Combined use of canaloplasty and trabeculotomy.</li> </ul> </li> <li>● Grabska-Liberek I, Duda P, Rogowska M, et al. (2022) 12-month interim results of a prospective study of patients with mild to moderate open-angle glaucoma undergoing combined viscodilation of Schlemm's canal and collector channels and 360° trabeculotomy as a standalone procedure or combined with cataract surgery. European journal of ophthalmology 32(1):309-15. <ul style="list-style-type: none"> <li>○ Included in the appendix of the original overview. Combined use of canaloplasty and trabeculotomy.</li> </ul> </li> <li>● Hirsch L, Cotliar J, Vold S et al. (2021) Canaloplasty and trabeculotomy ab interno</li> </ul>

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			<p>detachment, cataract formation, anterior synechiae, conjunctival leak incidence, corneal erosion, detectable conjunctival bleb, cells in the anterior chamber, iris incarceration and suture cheese wiring. Of these, Descemet's membrane detachment (DMD), conjunctival leak incidences, detectable conjunctival blebs and suture cheese wiring are related to the ab externo approach and have not been reported with ABiC. Consequently, in the last decade, there has been a major shift to the ab interno surgical approach to minimise conjunctival scarring and leverage the natural drainage system instead of creating a new conduit with filtration or tube shunt surgery.(3)</p> <p>There are two systems currently marketed that perform ABiC: the OMNI™ Surgical System (first approved in 2017) which allows two surgical procedures (ABiC and trabeculotomy) to be undertaken with a single device; and the iTrack® system (canaloplasty only), which has been available for over a decade for ab externo use and was first used with an ab interno approach in 2015. Comparative evidence on the ab externo and ab interno approaches demonstrate that while IOP lowering efficacy is comparable, safety is better for the ab interno versus the ab externo canaloplasty, with no serious adverse events (AEs) or AEs as a result of the iTrack® system reported when using the ab interno approach.</p> <p>Since ab interno is considered the safer approach, with less risk of long-term conjunctival complications than ab externo, we recommend that it should be assigned the same level of arrangement as the ab externo technique, to avoid ab externo canaloplasty being</p>	<p>with the OMNI system combined with cataract surgery in open angle glaucoma: 12-month outcomes from the ROMEO study. Journal of cataract and refractive surgery 47(7):907-15.</p> <ul style="list-style-type: none"> <li>○ Included in the appendix of the original overview. Combined use of canaloplasty and trabeculotomy.</li> <li>• Hughes T, Traynor M (2020) Clinical Results of Ab Interno Canaloplasty in Patients with Open-Angle Glaucoma. Clinical ophthalmology (Auckland, NZ) 14:3641-50. <ul style="list-style-type: none"> <li>○ Included in the key evidence of the original overview (Study 3).</li> </ul> </li> <li>• Klabe K, Kaymak H. (2021) Standalone Trabeculotomy and Viscodilation of Schlemm's Canal and Collector Channels in Open-Angle Glaucoma Using the OMNI Surgical System: 24-Month Outcomes. Clinical ophthalmology (Auckland, NZ) 15:3121-9. <ul style="list-style-type: none"> <li>○ Identified in the post-consultation literature search. Was included in the appendix of the updated overview. Combined use of canaloplasty and trabeculotomy.</li> </ul> </li> <li>• Pyfer MF, Gallardo M, Campbell A et al. (2021) Suppression of Diurnal (9AM-4PM) IOP Fluctuations with Minimally Invasive Glaucoma Surgery: An Analysis of Data from the Prospective, Multicenter, Single-Arm</li> </ul>

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			performed in preference to ab interno due to differences in recommendations for arrangements.	<p>GEMINI Study. Clinical ophthalmology (Auckland, NZ) 15:3931-8.</p> <ul style="list-style-type: none"> <li>○ Included in the appendix of the original overview. Combined use of canaloplasty and trabeculotomy.</li> <li>• Toneatto G, Zeppieri M, Papa V et al. (2022) 360° Ab-Interno Schlemm's Canal Viscodilation with OMNI Viscosurgical Systems for Open-Angle Glaucoma-Midterm Results. Journal of clinical medicine 11(1). <ul style="list-style-type: none"> <li>○ Included in the key evidence of the original overview (Study 5).</li> </ul> </li> <li>• Vold SD, Williamson BK, Hirsch L, et al. (2021) Canaloplasty and Trabeculotomy with the OMNI System in Pseudophakic Patients with Open-Angle Glaucoma: The ROMEO Study. Ophthalmology Glaucoma 4(2):173-81. <ul style="list-style-type: none"> <li>○ Included in the appendix of the original overview. Combined use of canaloplasty and trabeculotomy.</li> </ul> </li> <li>• Gallardo MJ. (2021) 24-month efficacy of viscodilation of Schlemm's canal and the distal outflow system with iTrack ab-interno canaloplasty for the treatment of primary open-angle glaucoma. Clin Ophthalmol.15:1591e1599. <ul style="list-style-type: none"> <li>○ Included in the key evidence of the original overview (Study 1).</li> </ul> </li> <li>• Gallardo MJ, Supnet RA, Ahmed IIK. (2018) Circumferential viscodilation of Schlemm's canal for openangle glaucoma: ab-interno vs</li> </ul>

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				<p>ab-externo canaloplasty with tensioning suture. Clinical ophthalmology 12:2493-8.</p> <ul style="list-style-type: none"> <li>○ Included in the appendix of the original overview. Studies with more people or longer follow up included.</li> </ul> <ul style="list-style-type: none"> <li>● Gallardo MJ, Supnet RA, Ahmed IIK. (2018) Viscodilation of Schlemm's canal for the reduction of IOP via an ab-interno approach. Clinical Ophthalmology 12:2149-55 <ul style="list-style-type: none"> <li>○ Included in the appendix of the original overview. Overlap with Gallardo (2021), with shorter follow up.</li> </ul> </li> <li>● Körber N. (2018) Ab interno canaloplasty for the treatment of glaucoma: a case series study. Spektrum der Augenheilkunde : Zeitschrift der Osterreichischen Ophthalmologischen Gesellschaft, OOG 32(6) <ul style="list-style-type: none"> <li>○ Included in the appendix of the original overview. Studies with more people or longer follow up included.</li> </ul> </li> <li>● Gillmann K, Aref A, Niegowski LJ, and Baumgartner JM. (2021) Combined ab interno viscocanaloplasty (ABiC) in open-angle glaucoma: 12-month outcomes. International Ophthalmology 41(10):3295-301. <ul style="list-style-type: none"> <li>○ Included in the key evidence of the original overview (Study 6).</li> </ul> </li> <li>● Koerber N, Ondrejka S. Four-Year Efficacy and Safety of iTrack Ab-interno Canaloplasty as a Standalone Procedure and Combined</li> </ul>

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
				<p>Please respond to all comments</p> <p>with Cataract Surgery in Open-Angle Glaucoma. Klinische Monatsblätter für Augenheilkunde.</p> <ul style="list-style-type: none"> <li>○ Identified in the post-consultation literature search and was included in the updated overview.</li> </ul> <p>The committee considered this comment but decided not to change the guidance.</p>
26	Consultee 3 Nova Eye Medical Ltd Company	Additional information	<p>We would like to draw attention to two recently published retrospective investigator-led studies, which provide real-world data in relation to the efficacy of ab-interno canaloplasty.</p> <p>The first study, performed by Mark J. Gallardo, MD (El Paso Eye Surgeons, Texas, USA) and published in the March 2022 issue of Ophthalmology Glaucoma, presents the 36-month results of a case series reporting on the reduction in mean IOP as compared to baseline, following ab-interno canaloplasty (performed with the iTrack™ canaloplasty device, Nova Eye Medical)(1). The reduction in the mean number of glaucoma medications was also reported. Forty-four (44) eyes of 44 patients were included in the study. Twenty-three (23) eyes underwent ab-interno canaloplasty as a standalone procedure (iTrack-alone group) and 21 eyes canaloplasty in combination with cataract surgery (iTrack+phaco group). There was a statistically significant reduction in mean IOP and mean number of medications between baseline and all post-operative visit (<math>p &lt; 0.0001</math>) either when ab-interno canaloplasty was performed as a standalone procedure or in combination with cataract surgery. Refer to Table 1 for summary of results.</p>	<p>Thank you for your comments.</p> <p>Consultee lists the following publications and describes efficacy results:</p> <ul style="list-style-type: none"> <li>• Gallardo MJ. (2022) 36-month effectiveness of ab-interno canaloplasty standalone versus combined with cataract surgery for the treatment of open-angle glaucoma. Ophthalmology Glaucoma <ul style="list-style-type: none"> <li>○ Identified in the post-consultation literature search and was included in the updated overview.</li> </ul> </li> <li>• Gallardo MJ. (2021) 24-month efficacy of viscodilation of Schlemm's canal and the distal outflow system with iTrack ab-interno canaloplasty for the treatment of primary open-angle glaucoma. Clin Ophthalmol.15:1591e1599. <ul style="list-style-type: none"> <li>○ Included in the key evidence of the original overview (Study 1).</li> </ul> </li> <li>• Davids AM, Pahlitzsch M, Boeker A, et al. (2019) Ab interno canaloplasty (ABiC)-12-</li> </ul>

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			<p>Mean <math>\pm</math> SD (n) of IOP and number of medications (Gallardo, 2022)</p> <p style="text-align: center;">All Eyes iTrack+Phaco iTrack-Alone</p> <p>IOP (mmHg)</p> <table border="0"> <tr> <td>baseline</td> <td>20.5 <math>\pm</math> 5.1 (44)</td> <td>20.0 <math>\pm</math> 3.9</td> <td>20.9 <math>\pm</math> 6.1</td> </tr> <tr> <td>12 mos</td> <td>13.3 <math>\pm</math> 2.1 (43)</td> <td>13.0 <math>\pm</math> 1.8</td> <td>13.7 <math>\pm</math> 2.3</td> </tr> <tr> <td>24 mos</td> <td>13.1 <math>\pm</math> 2.4 (36)</td> <td>12.4 <math>\pm</math> 1.5</td> <td>13.8 <math>\pm</math> 2.9</td> </tr> <tr> <td>36 mos</td> <td>13.3 <math>\pm</math> 2.1 (44)</td> <td>13.5 <math>\pm</math> 2.2</td> <td>13.2 <math>\pm</math> 2.1</td> </tr> </table> <p>Medications</p> <table border="0"> <tr> <td>baseline</td> <td>2.8 <math>\pm</math> 0.9 (44)</td> <td>2.5 <math>\pm</math> 1.1</td> <td>3.0 <math>\pm</math> 0.5</td> </tr> <tr> <td>12 mos</td> <td>1.1 <math>\pm</math> 1.1 (43)</td> <td>0.8 <math>\pm</math> 1.0</td> <td>1.5 <math>\pm</math> 1.2</td> </tr> <tr> <td>24 mos</td> <td>1.0 <math>\pm</math> 1.1 (39)</td> <td>0.8 <math>\pm</math> 1.0</td> <td>1.3 <math>\pm</math> 1.1</td> </tr> <tr> <td>36 mos</td> <td>1.3 <math>\pm</math> 1.3 (44)</td> <td>1.0 <math>\pm</math> 1.2</td> <td>1.6 <math>\pm</math> 1.4</td> </tr> </table> <p>Table 1. 36-month results of eyes treated with iTrack alone, iTrack combined with phacoemulsification, and all eyes considered together (Gallardo, 2022).</p> <p>The significant reductions in IOP observed at 12 months in both the iTrack-alone and the iTrack+phaco groups are comparable with the results of other 12-month studies, including a 24-month study by Gallardo (2) and a study by Davids et al (3) (device not specified), which compared ab-interno canaloplasty combined with cataract surgery (from a preoperative value of 19.7 <math>\pm</math>4.1 mmHg to 14.3 <math>\pm</math>2.5 mmHg at 12 months postoperatively) and as a standalone procedure (from a preoperative value of 20.2 <math>\pm</math>4.0 mmHg to 13.6 <math>\pm</math>3.6 mmHg at 12 months postoperatively). The recent results by Gallardo et al demonstrate that the reduction in mean IOP observed</p>	baseline	20.5 $\pm$ 5.1 (44)	20.0 $\pm$ 3.9	20.9 $\pm$ 6.1	12 mos	13.3 $\pm$ 2.1 (43)	13.0 $\pm$ 1.8	13.7 $\pm$ 2.3	24 mos	13.1 $\pm$ 2.4 (36)	12.4 $\pm$ 1.5	13.8 $\pm$ 2.9	36 mos	13.3 $\pm$ 2.1 (44)	13.5 $\pm$ 2.2	13.2 $\pm$ 2.1	baseline	2.8 $\pm$ 0.9 (44)	2.5 $\pm$ 1.1	3.0 $\pm$ 0.5	12 mos	1.1 $\pm$ 1.1 (43)	0.8 $\pm$ 1.0	1.5 $\pm$ 1.2	24 mos	1.0 $\pm$ 1.1 (39)	0.8 $\pm$ 1.0	1.3 $\pm$ 1.1	36 mos	1.3 $\pm$ 1.3 (44)	1.0 $\pm$ 1.2	1.6 $\pm$ 1.4	<p>month results of a new minimally invasive glaucoma surgery (MIGS). Graefes Arch Clin Exp Ophthalmol. 257:1947e1953.</p> <ul style="list-style-type: none"> <li>○ Included in the appendix of the original overview. Studies with more people or longer follow up were included.</li> <li>● Koerber N, Ondrejka S. (2022) Four-Year Efficacy and Safety of iTrack Ab-interno Canaloplasty as a Standalone Procedure and Combined with Cataract Surgery in Open-Angle Glaucoma. Klin Monbl Augenheilkd.</li> <li>○ Identified in the post-consultation literature search and was included in the updated overview.</li> </ul> <p>The committee considered this comment but decided not to change the guidance.</p>
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			<p>remains stable for up to 36 months, with no significant change from the 12-month visit.</p> <ol style="list-style-type: none"> <li>1. Gallardo MJ. 36-month effectiveness of ab-interno canaloplasty standalone versus combined with cataract surgery for the treatment of open-angle glaucoma. <i>Ophthalmol Glaucoma</i>. 2022 Feb 17:S2589-4196(22)00025-4. doi: 10.1016/j.ogla.2022.02.007. Epub ahead of print. PMID: 35183815. <a href="https://pubmed.ncbi.nlm.nih.gov/35183815/">https://pubmed.ncbi.nlm.nih.gov/35183815/</a></li> <li>2. Gallardo MJ. 24-month efficacy of viscodilation of Schlemm's canal and the distal outflow system with iTrack ab-interno canaloplasty for the treatment of primary open-angle glaucoma. <i>Clin Ophthalmol</i>. 2021;15:1591e1599.</li> <li>3. Davids AM, Pahlitzsch M, Boeker A, et al. Ab interno canaloplasty (ABiC)-12-month results of a new minimally invasive glaucoma surgery (MIGS). <i>Graefes Arch Clin Exp Ophthalmol</i>. 2019;257:1947e1953.</li> </ol> <p>The second study, performed by Prof. Norbert Koerber and Dr. Simon Ondrejka (Augenclintum Köln-Porz, Germany) and published in the April 2022 issue of <i>Klinische Monatsblätter für Augenheilkunde</i>, presents the 48-month results of a case series reporting on the reduction in mean IOP as compared to baseline, following ab-interno canaloplasty (performed with the iTrack™ canaloplasty device, Nova Eye Medical)(4). The reduction in the mean number of glaucoma medications was also reported.</p> <p>In the study by Koerber et al, a comparable reduction in mean IOP and mean number of medications was sustained 48 months postoperatively. Performed as a standalone procedure (n=4) or in conjunction with</p>	

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			<p>cataract surgery (n=23), ab-interno canaloplasty demonstrated a sustained reduction in IOP and in medication burden 4 years postoperatively. Refer to Table 2 for summary of results.</p> <p>Mean <math>\pm</math> SD (n) of IOP and number of medications (Koerber &amp; Ondrejka, 2022)</p> <p>All Eyes IOP (mmHg)</p> <p>baseline 19.85 <math>\pm</math> 5.2 (27) 12 mos 14.98 <math>\pm</math> 2.6 (26) 24 mos 15.58 <math>\pm</math> 3.3 (25) 36 mos 14.71 <math>\pm</math> 3.8 (21) 48 mos 14.56 <math>\pm</math> 3.0 (18)</p> <p>Medications</p> <p>baseline 1.93 <math>\pm</math> 1.0 (27) 12 mos 0.30 <math>\pm</math> 0.54 (27) 24 mos 0.40 <math>\pm</math> 0.64 (25) 36 mos 0.80 <math>\pm</math> 0.83 (20) 48 mos 0.89 <math>\pm</math> 0.83 (18)</p> <p>Table 2. 48-month results of all eyes considered together (Koerber &amp; Ondrejka, 2022).</p> <p>Approximately half of the eyes (n=13) in the study by Koerber et al were defined as controlled with medications at baseline, with an IOP equal to or less than 18 mmHg. In these eyes, ab-interno canaloplasty was performed to reduce patient reliance on medications due to intolerance or non-compliance, while maintaining IOP within target range. The mean</p>	

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			<p>number of medications for this group was <math>1.77 \pm 0.93</math> at baseline and reduced by more than 50% to <math>0.83 \pm 0.98</math> at 48 months. In addition, 50% of these eyes were on zero medications at the 48-month follow-up.</p> <p>4. Koerber N, Ondrejka S. Four-Year Efficacy and Safety of iTrack Ab-interno Canaloplasty as a Standalone Procedure and Combined with Cataract Surgery in Open-Angle Glaucoma. Klin Monbl Augenheilkd. 2022 Apr 14. English. doi: 10.1055/a-1737-4149. Epub ahead of print. PMID: 35426107. <a href="https://pubmed.ncbi.nlm.nih.gov/35426107/">https://pubmed.ncbi.nlm.nih.gov/35426107/</a></p>	Please respond to all comments
27	Consultee 3 Nova Eye Medical Ltd Company	Additional information	<p>We would also like to draw attention to a series of scientific podium presentations from the 2022 meeting of the American Society of Cataract and refractive Surgery (ASCRS), which provide further real-world evidence in relation to the efficacy outcomes of ab-interno canaloplasty (performed with the iTrack™ canaloplasty device, Nova Eye Medical). Please refer to the summary below:</p> <p>David Lubeck, MD (USA) and Robert Noecker, MD, MBA (USA)  “24-Month Evaluation of Endothelial Cell Density and Loss Following Ab-Interno Canaloplasty”  Session: Minimally Invasive Glaucoma Surgery (MIGS) III  Session Date: Sunday, April 24 2022  Session Time: 3:45-3:50pm  <a href="https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81062">https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81062</a></p> <p>James Murphy, MD (USA)</p>	<p>Thank you for your comments.</p> <p>Consultee lists several conference publications. Please note that the IP programme can only consider safety outcomes from non-peer-reviewed sources such as conference abstracts and cannot consider efficacy data.</p> <p>The following conference abstracts from the American Society of Cataract and refractive Surgery conference are listed:</p> <ul style="list-style-type: none"> <li>• David Lubeck, MD (USA) and Robert Noecker, MD, MBA (USA) “24-Month Evaluation of Endothelial Cell Density and Loss Following Ab-Interno Canaloplasty” <ul style="list-style-type: none"> <li>○ No safety outcomes presented.</li> </ul> </li> <li>• James Murphy, MD (USA) “Efficacy of Ab-Interno Canaloplasty Performed with and without GATT Following Previous Glaucoma</li> </ul>

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			<p>“Efficacy of Ab-Interno Canaloplasty Performed with and without GATT Following Previous Glaucoma Laser Treatment” Session: Minimally Invasive Glaucoma Surgery (MIGS) III Session Date: Sunday, April 24 2022 Session Time: 3:50-3:55pm <a href="https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81077">https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81077</a></p> <p>James Murphy, MD (USA) “Efficacy of Ab-Interno Canaloplasty Performed with or without GATT in Cases of Moderate Versus Severe Glaucoma” Session: Minimally Invasive Glaucoma Surgery (MIGS) III Session Date: Sunday, April 24 2022 Session Time: 3:58-4:03pm <a href="https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81078">https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81078</a></p> <p>Shamil Patel, MD (USA) “36-Month Comparison of Clinical and Safety Outcomes of Canaloplasty Performed as a Standalone Procedure or Combined with Cataract Surgery” Session: Glaucoma- Surgical Outcomes/Comparisons Session Date: Monday, April 25 2022 Session Time: 8:15-8:20am <a href="https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81056">https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81056</a></p> <p>Shamil Patel, MD (USA) “3-Year Clinical and Safety Outcomes of Canaloplasty</p>	<p>Laser Treatment” Session: Minimally Invasive Glaucoma Surgery (MIGS) III</p> <ul style="list-style-type: none"> <li>○ Abstract reports that ‘No adverse events were recorded’.</li> <li>● James Murphy, MD (USA) “Efficacy of Ab-Interno Canaloplasty Performed with or without GATT in Cases of Moderate Versus Severe Glaucoma” Session: Minimally Invasive Glaucoma Surgery (MIGS) III <ul style="list-style-type: none"> <li>○ Abstract reports that ‘No adverse events were recorded’.</li> </ul> </li> <li>● Shamil Patel, MD (USA) “36-Month Comparison of Clinical and Safety Outcomes of Canaloplasty Performed as a Standalone Procedure or Combined with Cataract Surgery” <ul style="list-style-type: none"> <li>○ Abstract reports 1 localised Descemet’s membrane detachment (combined group).</li> </ul> </li> <li>● Shamil Patel, MD (USA) 3-Year Clinical and Safety Outcomes of Canaloplasty Performed in Controlled and Uncontrolled Glaucoma Patients” Session: Glaucoma- Surgical Outcomes/Comparisons <ul style="list-style-type: none"> <li>○ Abstract reports that a localized Descemet’s membrane detachment occurred in the control group.</li> </ul> </li> <li>● George Reiss, MD (USA) and Shamil Patel, MD (USA) “Long-Term Clinical and Safety</li> </ul>

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			<p>Performed in Controlled and Uncontrolled Glaucoma Patients”            Session: Glaucoma- Surgical Outcomes/Comparisons            Session Date: Monday, April 25 2022            Session Time: 8:20-8:25am  <a href="https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81058">https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81058</a></p> <p>George Reiss, MD (USA) and Shamil Patel, MD (USA)            “Long-Term Clinical and Safety Outcomes of Canaloplasty Performed across All Grades of Glaucoma Severity”            Session: Glaucoma- Surgical Outcomes/Comparisons            Session Date: Monday, April 25 2022            Session Time: 8:28-8:33am  <a href="https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81059">https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81059</a></p> <p>Authors: Mohsain Gill, MD (USA), Mahmoud A. Khaimi (USA), David Murphy, MD (USA), Kai Ding, PhD (USA) and Kamram M. Riaz, MD (USA)            “Performing Ab-Interno Canaloplasty Post Keratoplasty- 12-month Outcomes”            Session: Minimally Invasive Glaucoma Surgery (MIGS) II            Session Date: Monday, April 25 2022            Session Time: 1:35-1:40pm  <a href="https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/80030">https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/80030</a></p> <p>Author: Mahmoud A Khaimi, MD (USA)            “Ab-Interno Canaloplasty Standalone Versus Combined with Cataract Surgery-</p>	<p>Outcomes of Canaloplasty Performed across All Grades of Glaucoma Severity”</p> <ul style="list-style-type: none"> <li>○ Abstract reports that there was 1 localised Descemet’s membrane detachment in the moderate group.</li> <li>● Mohsain Gill, MD (USA), Mahmoud A. Khaimi (USA), David Murphy, MD (USA), Kai Ding, PhD (USA) and Kamram M. Riaz, MD (USA) “Performing Ab-Interno Canaloplasty Post Keratoplasty- 12-month Outcomes”             <ul style="list-style-type: none"> <li>○ Abstract reports that 1 patient had a hyphema which required washout.</li> </ul> </li> <li>● Mahmoud A Khaimi, MD (USA) “Ab-Interno Canaloplasty Standalone Versus Combined with Cataract Surgery-36-month Outcomes in 1000+ eyes” Session: Minimally Invasive Glaucoma Surgery (MIGS) II             <ul style="list-style-type: none"> <li>○ Abstract reports that 99 eyes experienced adverse events such as postoperatively IOP spikes; 7 eyes had complications.</li> </ul> </li> <li>● Mahmoud A Khaimi, MD (USA) “Ab-Interno Canaloplasty in Patients with Primary Angle Closure- 12-month Outcomes” Session: Minimally Invasive Glaucoma Surgery (MIGS) II             <ul style="list-style-type: none"> <li>○ Abstract reports that no serious intra-operative or postoperative complications were reported.</li> </ul> </li> <li>● James Murphy, MD (USA) “Efficacy and Safety Profile of Ab-Interno Canaloplasty Performed with and without GATT – 12-</li> </ul>

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			<p>36-month Outcomes in 1000+ eyes” Session: Minimally Invasive Glaucoma Surgery (MIGS) II Session Date: Monday, April 25, 2022 Session Time: 1:40-1:45pm <a href="https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/80237">https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/80237</a></p> <p>Author: Mahmoud A Khaimi, MD (USA) “Ab-Interno Canaloplasty in Patients with Primary Angle Closure- 12-month Outcomes” Session: Minimally Invasive Glaucoma Surgery (MIGS) II Session Date: Monday April 25, 2022 Session Time: 1:45-1:50pm <a href="https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/80238">https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/80238</a></p> <p>Author: James Murphy, MD (USA) “Efficacy and Safety Profile of Ab-Interno Canaloplasty Performed with and without GATT – 12-Month Outcomes” Session: Minimally Invasive Glaucoma Surgery (MIGS) II Session Date: Monday, April 25 2022 Session Time: 1:50-1:55pm <a href="https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81075">https://ascrs.confex.com/ascrs/22am/meetingapp.cgi/Paper/81075</a></p>	<p>Please respond to all comments</p> <p>Month Outcomes” Session: Minimally Invasive Glaucoma Surgery (MIGS) II</p> <ul style="list-style-type: none"> <li>○ Abstract reports that no adverse events were recorded.</li> </ul> <p>The committee considered this comment but decided not to change the guidance.</p>
28	Consultee 3 Nova Eye Medical ltd	Additional information	We would like to draw attention to two recently published retrospective investigator-led studies, which provide real-world data in relation to the safety profile of ab-interno canaloplasty. In both studies, the frequency	Thank you for your comments. Consultee lists the following publications and describes safety results:

Com . no.	Consultee name and organisation	Sec. no.	Comments	Response
	Company		<p>of surgical and post-surgical complications reported was low, with no serious adverse events recorded.</p> <p>The first study, performed by Mark J. Gallardo, MD (El Paso Eye Surgeons, Texas, USA) and published in the March 2022 issue of Ophthalmology Glaucoma (1), In the first study, performed by Mark J. Gallardo, MD (El Paso Eye Surgeons, Texas, USA)(1), no serious adverse events were recorded over the 36-month follow-up period of the study. Of the total 81 eyes that underwent ab-interno canaloplasty in the study, 10 eyes (7 in the iTrack+phaco group and 3 in the iTrack-alone group) had a microhyphema (circulating red blood cells). Two eyes in the iTrack+phaco group had a layered hyphema (1 with a 1-mm hyphema and 1 with a 0.5-mm hyphema), and 1 eye in the standalone group had a layered hyphema of 0.5 mm. Two eyes in the iTrack phaco group had an IOP spike of 10 mmHg, 1 on 1 day and the other at 1 week postoperatively. One patient suffered from an IOP spike of &lt;10 mmHg on 1 day postoperatively in the standalone group.</p> <p>In the second study, performed by Prof. Norbert Koerber and Dr. Simon Ondrejka (Augencentrum Köln-Porz, Germany)(2) no significant complications were noted over the 48-month follow-up period of the study, except for a single case of limited descemetolysis near the limbus. This was likely caused by a slower withdrawal of the microcatheter (iTrack™ canaloplasty device, Nova Eye Medical) with a subsequent local over-delivery of the OVD in the canal that resulted in a detachment of the Descemet membrane. This resolved spontaneously after 6 weeks, with no sequalae and a stable IOP. No other adverse events were reported.</p>	<p>Please respond to all comments</p> <ul style="list-style-type: none"> <li>• Gallardo MJ. (2022) 36-month effectiveness of ab-interno canaloplasty standalone versus combined with cataract surgery for the treatment of open-angle glaucoma. Ophthalmology Glaucoma <ul style="list-style-type: none"> <li>○ Identified in the post-consultation literature search and was included in the updated overview.</li> </ul> </li> <li>• Koerber N, Ondrejka S. (2022) Four-Year Efficacy and Safety of iTrack Ab-interno Canaloplasty as a Standalone Procedure and Combined with Cataract Surgery in Open-Angle Glaucoma. Klin Monbl Augenheilkd. <ul style="list-style-type: none"> <li>○ Identified in the post-consultation literature search and was included in the updated overview.</li> </ul> </li> </ul> <p>The committee considered this comment but decided not to change the guidance.</p>

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			<p>Importantly, no secondary surgical interventions were required in order to control IOP in any of the eyes at the 12-, 24-, 36-, and 48-month timepoints.</p> <p>As described by Koerber et al (2), the illuminated LED tip of the iTrack™ canaloplasty device (Nova Eye Medical) allows the surgeon to track the microcatheter as it passes through the full length of Schlemm’s canal and thereby prevents misdirection into the collector channels or suprachoroidal space, improving the safety profile of the procedure as compared to canaloplasty devices that do not permit transscleral visualization.</p> <p>1. Gallardo MJ. 36-month effectiveness of ab-interno canaloplasty standalone versus combined with cataract surgery for the treatment of open-angle glaucoma. <i>Ophthalmol Glaucoma</i>. 2022 Feb 17:S2589-4196(22)00025-4. doi: 10.1016/j.ogla.2022.02.007. Epub ahead of print. PMID: 35183815. <a href="https://pubmed.ncbi.nlm.nih.gov/35183815/">https://pubmed.ncbi.nlm.nih.gov/35183815/</a></p> <p>2. Koerber N, Ondrejka S. Four-Year Efficacy and Safety of iTrack Ab-interno Canaloplasty as a Standalone Procedure and Combined with Cataract Surgery in Open-Angle Glaucoma. <i>Klin Monbl Augenheilkd</i>. 2022 Apr 14. English. doi: 10.1055/a-1737-4149. Epub ahead of print. PMID: 35426107. <a href="https://pubmed.ncbi.nlm.nih.gov/35426107/">https://pubmed.ncbi.nlm.nih.gov/35426107/</a></p>	

*"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."*