

Data Sheet INJECTORS I-glide

Product code: IGLMP – IGLMPX – IGLMPS

Model: I-glide (IGLMP)- I-glide micro (IGLMPX)- I-glide small (IGLMPS)

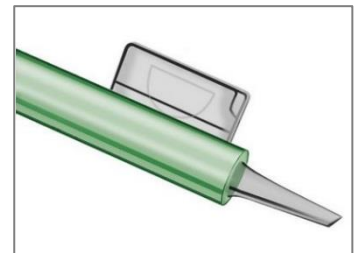
Manufacturer: Md Tech Srl - Via Fratelli Bandiera, Ncc - 80026 Casoria (Na), Campania Italia

Intended use: Injector for intraocular lens

Use: Intraoperative ophthalmic use

Disposable system for the injection of one-piece folding lenses, consisting of 3 elements.

- Disposable injector with silicone plunger
- Loading units
- Sterile disposable cartridge.
- Suitable for one-piece IOLs.



// General Features

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|---------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Material | Polypropylene and silicone, biocompatible with eye tissue |
| Incision size: | IGLMP: 2.2 mm IGLMPX: 2.0 mm IGLMPS: 2.4 mm |
| Reference Standard | Directive 93/42 CEE, UNI EN ISO:11979 |
| Class | II a ICIM, Notified Body n°0425, certif. N.0425-MED-003033-01 |
| Control performed | Cosmetic and defects |
| Packaging | Each injector is packaged individually in PETG and TYVEK blisters (primary packaging) and in cardboard boxes (secondary packaging). There are 10 injectors in each box |
| Product type | Medical device in compliance with the current legislation |
| Compatibility With Solutions | Product can be used with hyaluronic acid, balanced salt solution. It must not be used with acid or melted with other substances. |
| Shelf Life and Sterilization Method | The product is valid for 36 months from the date of sterilization and in any case until the expiry date shown on the packaging. The injector is sterilized with EtO in accordance with UNI EN ISO: 11135-1 / 2. The product is NOT RESTERILISABLE. |
| Presence of Latex | No |
| Information Reported on the Packaging | Batch number, expiry date, sterilization, manufacturer, CE mark. |

