















eIFU Single Use Instruments



Dokument: GEMMA_eIFU_V03, Stand 10-2021

 Manufacturer	GEMMA MEDICAL Service GmbH, Gmuender Strasse 6, 75181 Pforzheim, Germany Tel.: +49 7231 7801215 e-mail: info@gemma-medical.de www.gemma-medical.de		
Distributor	1stQ GmbH, Konrad-Zuse-Ring 23, 68163 Mannheim, Germany Tel: +49 621 78953790 e-mail: sales@1stq.de www.1stq.de		
For use by	Only for use by suitably trained and qualified medical professionals		
Intended Use	The instruments are intended for ophthalmological-surgical use. Hooks, spatulas: hand-held instruments for the manipulation of ocular tissue or the artificial intraocular lens to be implanted during cataract surgery Choppers: hand-held instruments for manipulation or sculpting of ocular tissue like the natural lens Forceps: hand-held instruments to grasp or hold ocular tissue or other medical devices such as sutures or IOLs Speculums: surgical instrument for retraction of the eyelids		
Contraindication	The single use instruments are not intended for use in surgery other than ophthalmology. The instruments are delivered sterile and may not be reprocessed or reused, see MDD statement. Use before expiration date.		
MDD Reuse Statement	If this product is reprocessed and/or reused, GEMMA MEDICAL cannot guarantee the functionality, material structure, or cleanliness or sterility of the product. Reuse could lead to illness, infection and/or injury to the patient or user. This product is labeled as 'single use' which is defined as a device intended to be used once only for a single patient.		
Warning	Used surgical instruments are contaminated. Disease may occur from injury. Dispose in a puncture resistant container. Refer to local regulatory guidelines.		
Symbols used:			
	Expiration Date		Medical Device
	Lot number		Unique Device Identifier
	Reference number		Manufacturing Date
	electronic Instruction For Use, see under www.gemma-medical.de		
	CE-marked		
	Do not reuse		
	Do not use in case of broken package		
	Store dry		
	Keep away from sunlight		
	Sterilized using ethylene oxide		