

BfArM case number 02689/21

Additional information to the L&R Field Safety Notice (FSN) for L&R sterile ophthalmic kitpacks/Raucosets containing B.Braun syringes or needles for intravitreal injection

Dear Sir or Madam

Today we would like to provide you with additional information, as some questions have arisen from the market in response to this FSN.

We would like to point out that the aforementioned Injekt syringes do not contain silicone oil but oleic acid amide as a lubricant - in contrast to the Omnifix products.

Since the use of both types of syringes in our Kitpack procedure packs, we have not received any complaints about complications after using the syringes for intravitreal injections.

The quality of the products has been confirmed to us by the manufacturer B.Braun to be flawless and in accordance with the standards.

It is still valid for both syringe types of the manufacturer B.Braun that they are not registered for intravitreal injection.

Table 1: List of affected products

Syringes	Lubricant
Injekt® Luer Solo Injekt® Luer Lock Solo Injekt® Luer Duo	Oleic acid amide
Injekt®-F Luer Solo Injekt®-F Luer Duo Injekt®-H Luer Solo Injekt®-H Luer Duo	Oleic acid amide
Omnifix®-F Luer Duo Omnifix®-F Luer Lock Solo Omnifix®-F Luer Solo Omnifix®-H Luer Solo Omnifix® Luer Duo Omnifix® Luer Lock Duo Omnifix® Luer Lock Solo Omnifix® Luer Solo	Silicone oil