

B. Braun Melsungen AG
Division Hospital Care
34209 Melsungen

To whom it may concern

Contact: Charlotte Wisker
Fon: +49 5661 71-5475
Fax: -
Email: charlotte_eileen.wisker@bbraun.com
Internet: <http://www.bbraun.de>
Date: July 18, 2025

CONFIRMATION

We,

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Germany

herewith confirm that the medical devices of the following product groups

Intrafix® Primeline
Intrafix® Primeline Type Flush
Intrafix® SafeSet
Intrafix® SafeSet Type Flush
Intrapur® Inline
Exadrop®

can be used up to 7 days.

The duration of use is dependent on the intended therapy according to the SPC (Summary of Product Characteristics) of the drug or solution. In general, change of IV administration sets should occur according national guidelines (e.g. CDC guideline) and / or hospital protocols. IV administration pressure set (P) should be changed after 24h at the latest in case it is used with an infusion pump. Intrapur® Inline should be changed after 24h at the latest.

For and on behalf of

B. Braun Melsungen AG

i. A.


Dr. Meike Junius
Senior Manager Regulatory Affairs
CoE Infusion & Pain Therapy

i. A.


Charlotte Wisker
Administrator Regulatory Affairs International
CoE Infusion & Pain Therapy