CS0270 – General Flip Cap Documentation Edition 2

Written by:
Ralf Dittmer
Manager Material Development Secondary Packaging
Date: 24 November 2014

Reviewed by:
Stefan Kühnle
Head of Quality Management
Date: 24. Nov. 2014

Approved by:
Renaud Janssen
Senior Manager Global Scientific Affairs
Date: 14/11/25

Approved by:
Bram Jongen
Head of Material Development CC & IS
Date: Nov 25, 2014

Distribution List: JROT, SSEV, SKEM, MWIL, DWOU

Table of Contents

1 Scope

This document covers all alu-plastic caps available from Datwyler Sealing Solutions. It does not cover alu-solo caps. The type-abbreviations and the names of the covered caps are shown in Table 1

Abbreviation	Meaning
FC	Flip Cap
SFC	Scoreline Flip Cap
UTO	Universal Tear-Off

Table 1: Caps covered in this document

2 Description

Flip cap seals are used to secure the rubber stopper onto injection vial; infusion bottles as well as IV funnels and injection ports on IV bags to maintain container closure seal integrity (CCSI).

Caps manufactured by Datwyler Sealing Solutions typically follow the ISO 8362-6, ISO 8362-7 respectively ISO 8536-7[1] standards. However certain dimensional differences to these ISO standards may apply. Please check the corresponding product drawing for details.

2.1 Functionality description

The caps are assembled from an aluminum cap and a plastic flip disc. In the case of the UTO cap an additional inner cap is added to hold the plastic cap. The assembled cap is crimped on an injection vial or infusion bottle to secure the rubber stopper which in turn maintains the integrity of the container/closure system. After removing the plastic disc on top of the flip cap, the piercing point in the rubber stopper is exposed to the injection needle respectively the infusion device or similar. UTO caps can be completely removed from the vial after opening of the plastic disc.

[1] ISO 8362-6 ‘Injection containers and accessories – Part 6: Caps made of aluminum-plastics combinations for injection vials’
ISO 8362-7 ‘Injection containers and accessories – Part 7: Injection caps made of aluminium-plastics combination without overlapping plastics part’
ISO 8536-7 ‘Infusion equipment for medical use – Part 7: Caps made of aluminum-plastics combination for infusion bottles’

2.2 Flip Caps (FC)

FC caps are available in sizes 13, 20, 28 and 32mm. They are assembled from aluminum caps with a plastic disc. In case of FC the plastic disc is equipped with fingers (amount of fingers varies with design), see Figure 1. The fingers are folded over by means of pressure and temperature during the assembly process to attach the plastic disc to the aluminum cap. The advantage of this design is the intrinsic tamper evidence. During opening of FC caps the plastic is completely separated from the aluminum which allows easy recycling of the different components.

Figure 1: FC components

2.3 Score-line Flip Caps (SFC)

SFC caps are available in sizes 13 and 20mm. They are assembled from aluminum caps with a plastic disc. In case of SFC the aluminum cap is equipped with a round pre-scored area which breaks off during opening of this cap, see Figure 2. The plastic disc is in this case equipped with a short plastic cylinder which is formed to a rivet, by means of pressure and temperature, during assembly of the caps. The opening force of this cap is determined by the score-line. Therefore this cap is especially suitable for sterilization processes.

Figure 2: Score-line flip caps

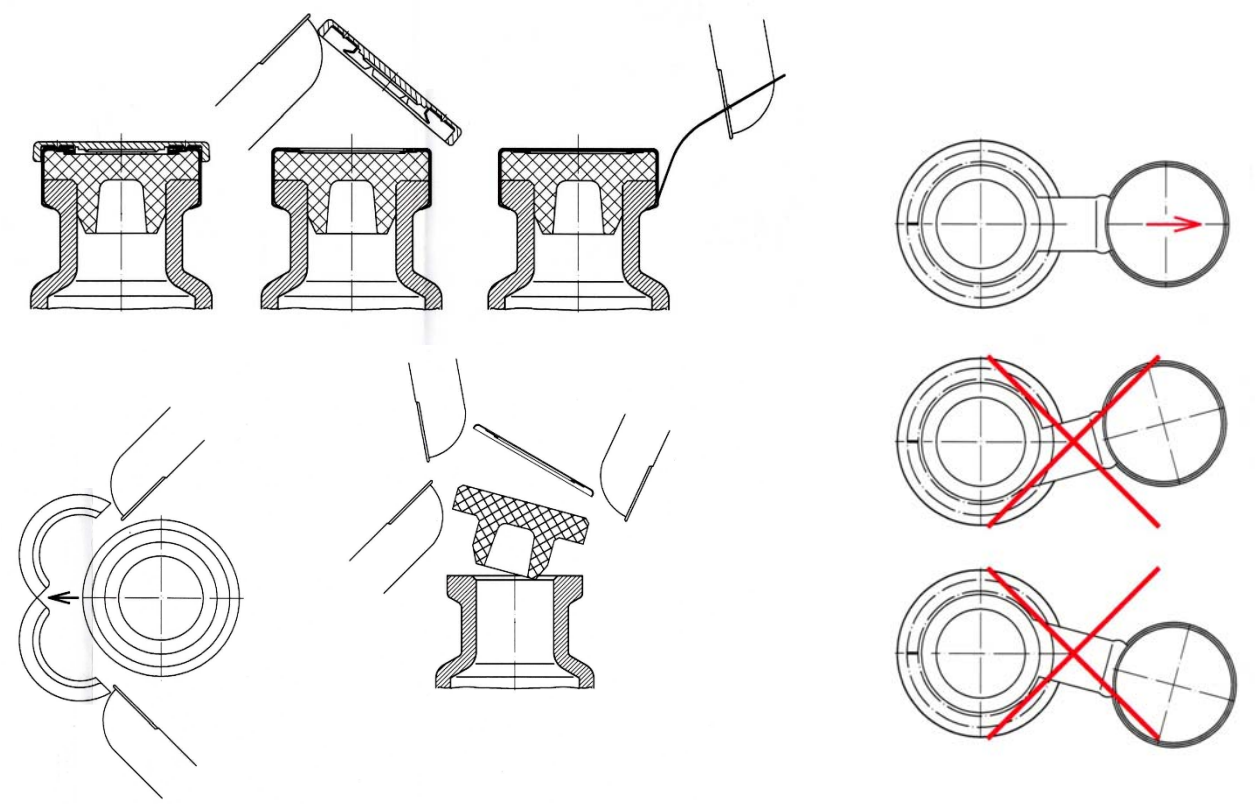
2.4 Universal tear off caps (UTO)

UTO caps are available in sizes 20, 28 and 32mm. They are assembled from two or three components. The UTO type made with 3 components consist of one aluminum cap with a ring, one aluminum inner cap and one plastic disc with finger design. The ring on the main aluminum cap allows for a complete removal of the cap, see the description below. The inner ring is needed in this design to hold the plastic disc.

The UTO type made from 2 components only consists of an aluminum cap and one plastic disc with a center rivet, see also Figure 2. After loosening of the plastic disc, the entire cap can be removed.

The opening mechanism of the UTO cap is shown in Figure 4

Figure 3: UTO cap after plastic disc removal



To open a UTO cap flip the plastic disc up and remove it. This will expose the piercing point of the rubber stopper. To completely remove the UTO cap with the stopper, pull up the metal ring and tear it straight down to break the metal cap. Remove the cap and the smaller inner cap from the stopper. Now the stopper can be completely removed.

Figure 4: Usage of 3 piece UTO cap

2.5 Difference between standard and flush design flip caps

The standard flip caps as seen in Figure 1 have a plastic disc which overlaps the aluminum cap by a certain distance. For applications with narrow vials Datwyler also produces flush design flip caps on which the plastic disc does not overlap the aluminum. This allows more stable transportation of the capped vials in the filling line.

Figure 5: Flush design flip caps

2.6 Opening forces

The opening forces of Datwyler flip caps follow ISO 8362-7 and ISO 8536-7 and are listed below.

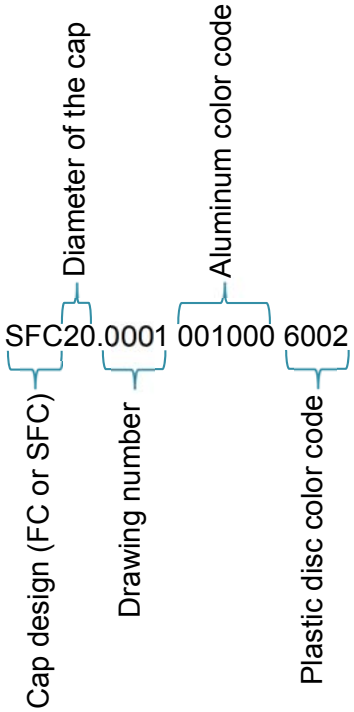
Cap diameter in mm	Maximum opening force in N
13	25
20	35
28	40
32	60

Table 2: Opening forces of flip caps according to ISO 8362-7 resp. 8536-7

2.7 Datwyler product codes for Flip Caps

The Flip Caps manufactured by Datwyler Sealing Solutions follow a certain part number coding. The part number of finger design Flip Caps starts with ‘FC’ while the part number of score-line flip caps starts with ‘SFC’. The next two digits of the part number define the diameter of the flip e.g. 20, 32mm followed by a period (‘.’). The next 4 digits are a sequential drawing number followed by a space and a 6 digit color code of the aluminum. The following 4 digit color code of the plastic disc is again separated by a space from the preceding number.

Example of Datwyler product code for Flip Caps:



2.8 Flip Cap production conditions

All Flip Cap production plants of Datwyler Sealing Solutons are certified according to ISO 9001 and in certain cases also ISO 15378. An up to date list of the current certifications of each production plant can be found on the website of Datwyler Sealing Solutions.
Datwyler flip caps are produced with dedicated, fully automatic, high-speed assembly machines according to specific diameter of the caps. All caps are controlled by a 2 color camera inspection system.

2.9 Flip Cap storage conditions

Aluminum and aluminum/plastic caps used for the capping of container/closure systems of parenteral pharmaceuticals are typically manufactured from epoxy lacquer coated aluminum and polypropylene (PP). The physical and functional properties of polymers (epoxy, PP) change over time. This ageing may be accelerated by inappropriate storage conditions.

Temperature, humidity, oxygen, ozone and light are factors, alone or in combination that may cause accelerated ageing in polymers.

The effects of these factors may be minimized by proper storage conditions.
The following guidelines may be useful in assuring the quality and functionality of aluminum and aluminum/plastic caps over time.

- Protection from oxygen and ozone: Typically aluminum and aluminum/plastic caps are packed in plastic bags. The caps should remain in their original packaging unopened until they are ready to be used.
- Protection from light: Aluminum and aluminum/plastic caps should remain in the bags in the unopened boxes. If removed from the box, the caps must be protected from exposure to sunlight and strong artificial light with a high ultra-violet content.
- Protection from temperature extremes: Storage at ambient temperatures are recommended. Permanent exposure to high temperatures may accelerate degradation. Lower temperatures will lead to temporarily increased brittleness of the parts.
- Protection from moisture: Wet and high humidity conditions should be avoided. Storage conditions must be such that condensation does not occur.
- Protection from deformation: Compression will cause caps to deform. Boxes should be stacked to utilize the strength of the corrugate to avoid compression of stored caps.
- Protection from other materials: Aluminum and aluminum/plastic caps should not have contact with solvents or their vapors or other chemicals. Caps should be stored away from chemical ingredients. The warehouse should be sufficiently ventilated.

Storage times should be minimized, first-in/first-out usage of stocks is highly recommended.

2.10 Printing on flip caps

Flip Caps are assembled from a deep drawn aluminum cap and a plastics disc made from PP polymer. Lubrication is applied on the aluminum for the deep drawing process, while PP by itself has a low surface tension. Both factors could make printing on the flip caps challenging. Pre-treatment (plasma, flame, …) of the Flip Caps could elevate the surface tension of the product to allow better ink adhesion. However, Datwyler has not tested the effect of pre-treatments on the quality or functionality of the Flip Caps.

It is therefore not recommended to print on the surface of flip caps. In any case thorough testing has to be performed by the user of the flip caps prior to printing or pre-treatment of the caps.

3 Material ingredients

3.1 Aluminum

Datwyler Sealing Solutions uses aluminum alloys that meet the specification of EN ISO 8872, for the production of flip caps. The alloy specifications of EN ISO 8872 is shown in Table 3.

Alloy	Tensile strength (UTS) in MPa	Yield strength in MPa
AlFeSi (annealed or coated)	100 – 150	> 80
AlFeSi	130 – 170	> 110
AlMnCu	140 – 180	> 120
The alloys above present only a selection of alloys typically used for the manufacturing of aluminum flip caps. Other alloys are permitted providing they meet the mechanical properties in this table.		

Table 3: Mechanical properties of aluminum alloys according to ISO 8872

3.2 Epoxy lacquer

The aluminum used for the manufacturing of flip caps is typically lacquered with epoxy based lacquer. This lacquer is, with one exception (see below), in compliance with the following regulations:

- Europe: 2007/19/CE, 2023/2006/CE
- Germany: BGA
- USA: FDA 21 § 175.300

Depending on customer specifications the lacquer may be pigmented for coloration. The lacquer application per square meter is fixed but may vary depending on color of the lacquer.

Black lacquer does not fulfill the above compliances due to the necessary amount of carbon black in the lacquer.

3.3 Polypropylene (PP)

PP homopolymer is used for the manufacturing of the flip disc. The used PP compounds meet the requirements on materials and articles intended for contact with foodstuffs according to Regulation (EC) 1935/2004 of the European Parliament and of the Council, as well as according to Commission Regulation (EU) No 10/2011 including changes and additions.

3.4 Lubricants

The lubricants used for the manufacturing of the aluminum caps are in compliance with FDA CFR 21 § 178.3910. The level of remaining lubricants, on the product, does not exceed the level of 0.2 mg/inch² (0.031 mg/cm²).

3.5 Heavy metals

Flip Caps manufactured by Datwyler Sealing Solutions fulfil the European Community Guideline CEE 94/62 for heavy metals in packaging materials and the CONEG Regulation on Reduction of Toxics in Packaging Law.

Both directives state that packaging components should not contain more than 100 ppm of Lead (Pb), Cadmium (Cd), Mercury (Hg) and Hexavalent Chromium (VI) (Cr).

3.6 Bisphenol A (BPA)

Bisphenol A, CAS# 80-05-7 is used to produce certain plastics and epoxy resins. Epoxy resins containing BPA are used as coatings on the inside of many food and beverage cans as well as a coating for the aluminum used for the manufacturing of flip caps. BPA is mostly consumed during the curing (polyaddition) of the lacquer.

Datwyler Sealing Solutions conducted an extraction study on epoxy lacquered aluminum caps of one specific color in June of 2012. Thermal Desorption – Gas Chromatography / Mass Spectroscopy (TD-GC/MS) was used for this study. As a result, under the conditions of the test, BPA was found at a level of only 0.02µg/cm² of lacquered surface in water.

However, Datwyler Sealing Solutions does not test the lacquered aluminum for Bisphenol A on a regular basis.
Considering the low level of extractable BPA and the fact that the lacquered flip caps, as secondary packaging, have no direct contact to the product inside the sealed vial, the risk for migration of BPA into the bottled drug is deemed very unlikely.

3.7 BSE/TSE

The Polypropylene (PP) plastic used for the production of flip caps may be produced with additives that derive from tallow. The tallow derived raw materials used in the PP fulfill the requirements laid down in the Note for Guidance, EMEA/410/01, rev. 3, part 6.4 (Tallow Derivatives). Our supplier declares that the tallow derivatives are Category 3 materials and are manufactured under the conditions given in the aforementioned Note for Guidance.

3.8 Phthalates

Phthalates are substances added to certain plastics, typically PVC, to increase their flexibility, transparency, durability, and longevity.
Neither the polypropylene nor the lacquer composition on the aluminum has phthalates intentionally added. However, the presence of traces of these substances, in the amount of ppm, deriving from raw material impurities, manufacturing equipment, processes or as omnipresent contaminations, can’t be completely excluded.

3.9 Asbestos

Asbestos is a naturally occurring silicate mineral. The prolonged inhalation of asbestos fibers can cause serious illnesses including malignant lung cancer, mesothelioma, and asbestosis.
Datwyler Sealing Solutions does not use asbestos in the production of flip caps nor are asbestos containing raw materials used in the flip cap production.

3.10 Calcium

During the production of aluminum caps or flip caps no calcium is intentionally added to the products. However, it cannot be completely excluded that traces of calcium enter the product during the production process of the used raw materials.

3.11 Chlorine

Chlorine in plastics is mainly found in PVC. However, no PVC or other chlorine containing substances are being used for the manufacturing of flip caps at Datwyler Pharma Packaging. The absence has not been checked by tests.

3.12 Polychlorinated and Polybrominated Diphenyl

Datwyler Pharma Packaging does not intentionally use or add polychlorinated and polybrominated diphenyl or any of its derivatives in the production of flip caps. However, the presence of negligibly traces due to, among other things, impurities in the products supplied by external parties, cannot be completely excluded. The absence has not been checked by tests.

3.13 Conflict minerals

Conflict minerals are minerals mined in conditions of armed conflict and human rights abuses. These minerals typically include columbite-tantalite, gold, wolframite, derivative of tantalum, tin, and tungsten. No conflict minerals are intentionally added during the production of flip caps. Datwyler Sealing Solutions is not aware of conflict minerals being used in the manufacturing of the raw materials used for the manufacturing of flip caps.

3.14 Latex, gluten and lactose

Latex, gluten and lactose may cause allergic reactions for certain humans.
Datwyler Sealing Solutions does not use latex, gluten or lactose for the production of flip caps. However, the presence of one or more of the above substances in the production area cannot be completely excluded (gloves, etc.).

4 Sterilization

4.1 Steam sterilization

The materials used for the manufacturing of flip caps are resistant to terminal sterilization at 121°C for 30 minutes. To prevent premature opening of the flip caps during a terminal steam sterilization process sufficient counter pressure needs to be used in the autoclave according to the filling level of the vial.

4.2 Radiation sterilization

Datwyler Sealing Solutions offers Ready To Use (RTU) flip caps that are gamma sterilized according to a validated process. It is not recommended to irradiate standard, non-RTU, flip caps by gamma or beta sterilization.

5 Packaging

The packaging specification varies depending on product and customer specification.

5.1 Shelf Life of non-irradiated flip caps

The recommended shelf life for non-irradiated flip caps before use (capping) is 2 years. After capping the additional recommended shelf life is 5 years.
This recommendation is based on a theoretical approach: Aluminum materials are not suspected to have changes in properties over this time period and also, given the requirements to the PP disc it is not assumed that physical properties would change significantly if stored under normal conditions, see 2.9.

5.2 Shelf life of RTU Flip Caps

The shelf life for RTU flip caps is 2 years before capping.

6 Defect classes and corresponding AQL levels

Defect class	AQL	Examples
Critical defect	0.01	Mix up, wrong ID
Major defect A	0.25	Dimensional deviation, gross contamination
Major defect B	0.65	Contamination, dirt, color deviations
Minor defect A	2.5	Cosmetic defects without effect on functionality

The standard AQL levels are intended for standard use. They can be changed as a result of specific customer agreements.

7 History

Edition (issue date)	Change (chapter + change)	Comment (rationale)
1 (June 28, 2013)	N/A	First edition
2 (November 21, 2014)	Added disclaimer regarding document distribution on front page	Addition
	1 - Added Scope	Addition
	2.1 – Added UTO in properties	Addition
	2.2 – Description of FC added	Addition
	2.3 – Description of SFC added	Addition
	Difference between FC and SFC deleted	Replaced by 2.2 and 2.3
	2.4 – Description of UTO added	Addition
	2.9 - 3rd bullet point : reformulated text	General caution statement
	5.1 – Shelf life changed from 3+4 to 2+5 2.9 –	Aligned with rubber